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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,649	07/28/2003	Lena Edelman	02356.0083	4213

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,649	EDELMAN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1-5, 6, 8, 9, 11, 26 and 31, drawn to a method to induce apoptosis using a *tox* protein.
- Group II, claims 1-5, 7, 8, 10, 11, 27, 28 and 32, drawn to a method to prevent apoptosis using a *save* protein.
- Group III, claims 12, 13, 15, 16, 18 and 34, drawn to a *tox* molecule.
- Group IV, claims 12, 14, 15, 17, 19 and 34, drawn to a *save* molecule.
- Group V, claims 20 and 23, drawn to a vector encoding a *tox* molecule.
- Group VI, claims 20 and 23, drawn to a vector encoding a *save* molecule.
- Group VII, claims 21 and 22, drawn to a monoclonal antibody and hybridoma cell line producing the antibody.
- Group VIII, claim 24, drawn to a cancer cell having a tumor-associated antigen and a *tox* molecule.
- Group IX, claim 24, drawn to a cancer cell having a tumor-associated antigen and a *save* molecule.
- Group X, claim 25, drawn to a method to detect a cancer cell having a tumor-associated antigen using a *tox* molecule.
- Group XI, claim 25, drawn to a method to detect a cancer cell having a tumor-associated antigen using a *save* molecule.

- Group XII, claims 29 and 30, drawn to a method to identifying an agent that interacts with the activity of the PTPC complex using a *tox* molecule.
- Group XIII, claims 29 and 30, drawn to a method to identifying an agent that interacts with the activity of the PTPC complex using a *save* molecule.
- Group XIV, claim 31, drawn to a method to identify *tox*-like mitochondrial antigens.
- Group XV, claim 32, drawn to a method to identify *save*-like mitochondrial antigens.

2. The asserted special technical feature of the instant claim set is a *tox* molecule or a *save* molecule fused to a target protein. The prior art anticipates this feature. Yarkoni *et al.* (WO 99/45128, cited in IDS) teaches chimeric proteins with cell-targeting specificity and apoptosis-inducing activities (see abstract). Therefore, the claims lack unity of invention.

3. The inventions are distinct, each from the other because of the following reasons:

a) Groups I and II are distinct methods. The inventions are drawn to methods of inducing apoptosis and preventing apoptosis. The act of inducing apoptosis involves the killing of cells, while the act of preventing apoptosis involves saving cells from apoptosis.

b) Groups III and IV are distinct products. *Tox* molecules and *save* molecules are not identical, nor do they function in the same manner. *Tox* molecules induce apoptosis while *save* molecules prevent apoptosis. While both are used for affecting apoptosis, the molecules themselves are not necessarily related structurally. In the same way, Groups V and VI are distinct nucleotide molecules that encode different proteins having different functions.

c) Groups VIII and IX are distinct products, drawn to cancer cells having either *tox* or *save* molecules on their surface. While the cells themselves are the same, the differing *tox/save* molecule renders the cells patentably distinct for the reasons above.

d) Groups (I and II) and (III and IV) are related as product and process of using. The product can be used in a materially distinct method, such as detecting and quantifying antibodies in an assay.

e) Groups (I and II) and (V-IX) are unrelated products. The vectors and host cells encoding *tox* and *save* molecules are not directly required in the method steps of inducing or preventing apoptosis. The antibodies and hybridomas are not directly required to practice the methods of inducing or preventing apoptosis. The cancer cells are not required to practice the methods of inducing or preventing.

f) Groups (I and II) and (X-XV) are drawn to distinct methods. The methods of preventing or inducing apoptosis do not share method steps with methods of detecting cancer cells, identifying agents that interact with the PTPC complex or identifying *tox*-like or *save*-like mitochondrial agents.

g) Groups (III and IV) and (V and VI) are related as protein and DNA encoding the protein, respectively. Proteins and nucleic acid are chemically distinct structures. Inventions (III and IV) and (V and VI) are patentably distinct products. The polypeptides and polynucleotides are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. In addition, while the polypeptides can made by methods using some, but not all, of the polynucleotides, it can also be recovered from a natural source using by

biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups (III and IV) and (V and VI) are patentably distinct.

h) Groups (III and IV) and VII are distinct products, drawn to proteins and antibodies. While the inventions of both Groups (III and IV) and VII are polypeptides, in this instance the polypeptides are single chain molecules that function as apoptosis agents, whereas the antibodies encompass IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptides and the antibodies are structurally distinct molecules. In this case, the polypeptides are large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibodies are defined in terms of its binding specificity to a small structure within SEQ ID NO: 2. Thus immunization with the polypeptides would result in the production of antibodies outside the scope of Group VII (*i.e.*, antibodies that bind to regions other than residues 110-118 of SEQ ID NO: 2). Therefore the polypeptide and antibody are patentably distinct.

i) Groups (III and IV) and (VIII and IX) are distinct products, drawn to proteins and cells. Proteins are composed of amino acids that form polypeptides. Cells are complex structures comprising numerous structural proteins and non-structural proteins that are not related to the claimed products.

j) Groups (V and VI) and VII are distinct products, drawn to vectors (DNA) encoding *tox* and *save* molecules, and antibodies, respectively. The polynucleotides/vectors and the antibodies are patentably distinct for the following reasons. The antibodies include, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions,

and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Antibodies are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. In the present claims, a polynucleotide of Groups (V and VI) will not encode an antibody of group VII, and the antibody cannot be encoded by the polynucleotide. Therefore the antibody and polynucleotide are patentably distinct.

k) Groups (VIII and IX) and VII are distinct products, drawn to cells and antibodies. The structures of cells and antibodies are vastly different. Cells are comprised of numerous structural and non-structural proteins that work in sync with each other to operate as a living cell. Antibodies are complex molecules that do not have nonstructural proteins or function as a living molecule.

l) Groups (III-VI) and Groups (X-XV) are related as product and process of using, respectively. The *tox* and *save* molecules of Groups III and IV (and respective vectors of Groups V and VI) can be used in materially different processes than those of Groups X-XV. The *tox* and *save* molecules or vectors thereof can be used in an assay to detect and quantify antibodies.

m) Groups (VIII and IX) and (X and XI) are related as product and process of using. The cells can be used in a materially different method such as production of antigen, rather than assay methods.

n) Groups (VIII and IX) and (XII-XV) are unrelated. The products of Groups VIII and IX, cancer cells, are not required to practice the invention of Groups XII and XV. Cancer cells are not required to identify agents or antigens.

o) Groups XIV and XV are distinct methods, drawn to identifying antigens that interact either with *tox* or *save* molecules. Antigens that interact with *tox* are not the same as those that interact with *save*. Methods to identify those different antigens are patentably distinct methods.

p) Groups (X and XI), (XII and XIII) and (XIV and XV) are distinct methods. The methods of detecting cancer cells is not required in a method of identify agents that interact with a complex. The method of detecting cancer cell is not required in a method to detect mitochondrial antigens. The method of identifying agents that interact with a complex does not require the method steps of a method to detect mitochondrial agents.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen
December 5, 2005